UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------------------------------|----------------------|---------------------|------------------|
| 10/702,316 | 11/05/2003 | Norman Milstein | M 6212C-NHG/ST | 7930 |
| | 7590 08/21/2007 ORPORATION EXAMINER | | | INER |
| PATENT DEPARTMENT | | | HANDY, NIKKI R | |
| 300 BROOKSI AMBLER, PA | | • | ART UNIT | PAPER NUMBER |
| ŕ | | | 1616 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 08/21/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | |
|--|---|---|---|--|--|
| | | 10/702,316 | MILSTEIN ET AL. | | |
| • | Office Action Summary | Examiner | Art Unit | | |
| | | Nikki Handy | 1616 | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the o | correspondence address | | |
| | | ZIS SET TO EVRIPE 2 MONTH | (S) OB THIRTY (30) DAVS | | |
| WHIC - Exte after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAY INSIGNS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Of period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE | N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | |
| Status | | | • | | |
| 1)⊠ | Responsive to communication(s) filed on 22 Fe | ebruary 2007. | • | | |
| 2a)⊠ | This action is FINAL . 2b) This action is non-final. | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| | closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 4 | 53 O.G. 213. | | |
| Disposit | ion of Claims | | | | |
| 4) 🛛 | Claim(s) 93-110 is/are pending in the application | on. | | | |
| , | 4a) Of the above claim(s) <u>1-92</u> is/are withdrawr | | | | |
| 5) | Claim(s) is/are allowed. | | | | |
| 6)⊠ | Claim(s) 93-110 is/are rejected. | · | | | |
| 7) | Claim(s) is/are objected to. | | | | |
| 8)[| Claim(s) are subject to restriction and/o | r election requirement. | | | |
| Applicat | ion Papers | | | | |
| 9) | The specification is objected to by the Examine | г. | · | | |
| 10) | The drawing(s) filed on is/are: a) acc | epted or b) objected to by the | Examiner. | | |
| • | Applicant may not request that any objection to the | | | | |
| · | Replacement drawing sheet(s) including the correct | ion is required if the drawing(s) is ob | pjected to. See 37 CFR 1.121(d). | | |
| 11) | The oath or declaration is objected to by the Ex | aminer. Note the attached Office | e Action or form PTO-152. | | |
| Priority (| under 35 U.S.C. § 119 | | | | |
| 12) | Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119(a | n)-(d) or (f). | | |
| - | ☐ All b)☐ Some * c)☐ None of: | | , , , , , | | |
| · | 1. Certified copies of the priority document | s have been received. | | | |
| | 2. Certified copies of the priority document | s have been received in Applicat | ion No | | |
| • | 3. Copies of the certified copies of the prior | rity documents have been receive | ed in this National Stage | | |
| | application from the International Bureau | ı (PCT Rule 17.2(a)). | | | |
| * (| See the attached detailed Office action for a list | of the certified copies not receive | ed. | | |
| • | | | | | |
| • | | | | | |
| Attachmer | nt(s) | _ | | | |
| | ce of References Cited (PTO-892) | 4) Interview Summary Paper No(s)/Mail D | | | |
| | ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) | 5) Notice of Informal F | | | |
| | er No(s)/Mail Date | 6) | | | |

Application/Control Number: 10/702,316

Art Unit: 1616

DETAILED ACTION

Status of Claims

Claims 93-110 are pending. Claims 1-92 have been cancelled. Receipt of Applicants' remarks/arguments filed on February 22, 2007 are acknowledged.

Response to Restriction Requirement

It should be noted that Applicants' have requested reconsideration and withdrawal of the Restriction Requirement of Claims 93-109 and Claim 110. The traversal is on the ground(s) that Claim 110 contains all of the limitations of Claim 93, the independent claim directed to the food additive composition. See elements (a), (b), (c) and (d) of the food additive composition recited in Claims 93 and 110. The traversal has been found persuasive. There is rejoinder of Claims 93-109 and Claim 110. Therefore, all claims will be examined.

Provisional Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

Application/Control Number: 10/702,316

Art Unit: 1616

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937,214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37CFR 3.73(b).

Claims 93-109 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 8, 11, 12, and 13-18 of U.S. Patent No. 6,394,230 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both application and USPN '230 claim a food additive composition that is useful for lowering cholesterol. The scope of the application claims differs from the USPN '230 claims in that the USPN '230 makes claim to a food additive comprising a reaction mixture formed by reacting at least one member selected from the group consisting of carboxylic acids and carboxylic acid esters in the presence of a catalytically effective amount of a catalyst selected from

Art Unit: 1616

the group consisting of calcium oxide, calcium hydroxide, a calcium salt of a carboxylic acid, magnesium hydroxide and combinations thereof, wherein said reaction mixture includes at least a portion of said catalyst, whereas, the instant application claims a food additive composition comprising: (a) an edible solubilizing agent; (b) an effective amount of a suitable disperant; (c) an effective amount of an antioxidant; and (d) an ester prepared by reacting at least one first reactant selected from the group consisting of sterols, stanols, and combinations thereof with at least one second reactant selected from the group consisting of Carboxylic acids and carboxylic acid esters in the presence of a catalytically effective amount of a catalyst selected from the group consisting of calcium oxide, calcium hydroxide, a calcium salt of a carboxylic acid, magnesium hydroxide and combinations thereof. USPN '230 recites the following: a food additive comprising a reaction mixture, etc. The terminology, comprising, is a term which allows for the inclusion of unrecited components. The additional unrecited components in the instant claims are an edible solubilizing agent, an effective amount of a suitable dispersant, and an effective amount of an antioxidant. It would be obvious to one of ordinary skill in the art to include the additional ingredients because the USPN '230 makes claim to the food additive comprising a reaction mixture by reacting at least one member selected from the group consisting of sterols, stanols and combinations thereof with at least one member selected from the group consisting of carboxylic acids and carboxylic acid esters in the presence of a catalytically effective amount of a catalyst alone. The USPN '230 inherently claims the invention of the instant application where

Art Unit: 1616

the food additive composition is employed with an edible solubilizing agent, an effective amount of a suitable dispersant, and an effective amount of an antioxidant.

Response to Applicant's Arguments

Applicants' arguments filed on February 22, 2006 have been fully considered but they are not persuasive. Applicants' argue that (1) during a Telephonic Interview, the Double Patenting rejection was submitted in error and is improper because the present application is a Divisional application of U.S. Application No. 6,394,230 B1 (hereinafter '230). The subject matter of the present claims was the subject of a Restriction Requirement in '230, (2) the Office issued a Requirement for Restriction in '230. The Double Patenting rejection of the present application over '230 is prohibited under 35 USC Section 121 and should be withdrawn. Applicant is requesting withdrawal of the Double Patenting rejection of Claims 93-109. The Examiner respectfully disagrees. The subject matter ((in Original Claim 28 of Application Serial No. 09/083,584), where Formula I (carboxylic acid and carboxylic acid esters) and Formula II (stanol) of patent '230 and also Original Claim 28, Formula I (carboxylic acid and carboxylic acid esters) and Formula III (sterol)) of patent '230, was not restricted in the parent application, Serial Application No. 09/083,584. Furthermore, since Claim 110 encompasses all the limitations of Claim 93 and has been rejoined with Claims 93-109, Claim 110 is rejected under Double Patenting also. In addition, the Double Patenting rejection of Claims 93-110 is maintained.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki Handy whose telephone number is (571) 272-9923. The examiner can normally be reached on Monday-Friday 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1616

Nikki Handy Patent Examiner Art Unit 1616

Johann R. Richter

Supervisory Patent Examiner Technology Center 1600